

Serial No.: 10/051,662

Our File No. 31140-B

CLAIMS

1-34. (canceled)

35. (previously presented) A pharmaceutical composition comprising a Vitamin D compound and a progestin product in a single unit dosage.

36. (previously presented) The pharmaceutical composition of claim 35 wherein said progestin product is selected from the group consisting of progesterone, pregnanes, estranes, and gonanes.

37. (previously presented) The pharmaceutical composition of claim 36 wherein the Vitamin D compound is present at a dosage equivalent of from 0.0001 to 1.0 mg. 1,25-dihydroxyvitamin D₃/kg of body weight and wherein the progestin product is present at a dosage less than or equal to a dosage equivalent to 10.0 mg of norethindrone.

38. (previously presented) The pharmaceutical composition of claim 37 wherein the Vitamin D compound is present at a dosage equivalent of from 0.005 to 0.1 mg. 1,25-dihydroxyvitamin D₃/kg of body weight and wherein the progestin product is present at a dosage less than or equal to a dosage equivalent to 1.0 mg of norethindrone.

39. (canceled)

40. (withdrawn) The pharmaceutical composition in claim 35 wherein said hormone product compound comprises estrogen.

41. (withdrawn) The pharmaceutical composition of claim 40 wherein the Vitamin D compound is present at a dosage equivalent of from 0.0001 to 1.0 mg 1,25-dihydroxyvitamin D₃/kg of body weight.

42. (withdrawn) The pharmaceutical composition of claim 41 wherein the Vitamin D compound is present at a dosage equivalent of from 0.005 to 0.1 mg 1,25-dihydroxyvitamin D₃/kg of body weight.

43. (withdrawn) The composition of claim 36 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

44. (withdrawn) The composition of claim 40 wherein such estrogen is conjugated equine estrogen.

45. (previously presented) A contraceptive regimen comprising a Vitamin D compound and a progestin product wherein the regimen is contraceptively effective.

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46. (previously presented) The regimen of claim 45 wherein said progestin product is selected from the group consisting of progesterone, pregnanes, estranes, and gonanes.

47. (withdrawn) The regimen of claim 46 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

48. (withdrawn) The regimen of claim 47 wherein said progestin is levonorgestrel.

49. (previously presented) The regimen of claim 46 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.

50. (withdrawn) The regimen of claim 45 wherein said hormone product includes a estrogen product.

51. (withdrawn) The regimen of claim 50 including a composition wherein Vitamin D compound and said estrogen are present in a single unit dosage.

52. (withdrawn) The regimen of claim 50 further including a progestin.

53. (withdrawn) The regimen of claim 52 wherein said Vitamin D compound, said progestin and said estrogen are present in a single unit dosage.

54. (withdrawn) The regimen of claim 53 wherein said progestin is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

55. (previously presented) A hormone replacement therapy regimen for administration to a post-menopausal woman comprising a composition including Vitamin D compound and a progestin product selected from the group consisted of progesterone, pregnanes, estranes, and gonanes, wherein the Vitamin D compound is present at a dosage equivalent of from 0.0001 to 1.0 mg 1,25 dihydroxyvitamin D₃ per kg of body weight.

56. (previously presented) The regimen of claim 55 wherein in the Vitamin D compound is present at a dosage equivalent of from 0.005 to 0.75 mg of 1,25 dihydroxyvitamin D₃ per kg of body weight.

57. (previously presented) The regimen of claim 55 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

58. (previously presented) The regimen of claim 57 wherein said progestin is norgestrel.

59. (previously presented) The regimen of claim 56 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.

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60. (withdrawn) The regimen of claim 55 wherein said hormone product includes a estrogen product.

61. (withdrawn) The regimen of claim 60 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.

62. (withdrawn) The regimen of claim 60 further including a progestin.

63. (withdrawn) The regimen of claim 62 herein said Vitamin D compound, said progestin and said estrogen are present in a single unit dosage.

64. (withdrawn) The regimen of claim 63 wherein said progestin is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

65. (previously presented) The regimen of claim 55 wherein said progestin product is a gonane.

66. (previously presented) The regimen of claim 56 wherein the Vitamin D compound is administered at a dosage equivalent of from 0.05 to 0.5 mg 1.25 dihydroxyvitamin D₃ per kg of body weight.

67. (previously presented) A hormone replacement therapy regimen for administration to a post-menopausal woman comprising a composition including Vitamin D compound and a progestin product selected from the group consisted of progesterone, pregnanes, estranes, and gonanes, wherein the Vitamin D compound is 1.25 dihydroxyvitamin D₃ administered at a dosage equivalent to 400 I.U.

68. (previously presented) The regimen of claim 67 wherein the Vitamin D compound is 1.25 dihydroxyvitamin D₃ administered at a dosage equivalent to 2000 I.U.

69. (previously presented) The regimen of claim 68 wherein the Vitamin D compound is 1.25 dihydroxyvitamin D₃ administered at a dosage equivalent to 4000 I.U.

70. (previously presented) The regimen of claim 67 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.

71. (previously presented) The regimen of claim 67 wherein said progestin product is a gonane.

72. (previously presented) The regimen of claim 67 wherein said progestin is a norgestrel.

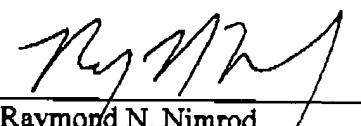
73. (previously presented) The regimen of claim 67 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.

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74. (new) A pharmaceutical product comprising a package containing 28 daily sequential dosage units, said daily sequential dosage units comprising a contraceptively effective regimen, said regimen further comprising a Vitamin D compound and a progestin product, and wherein at least one and up to seven of the daily sequential dosage units do not contain any progestin product.

Respectfully submitted,

Dated: May 23, 2005

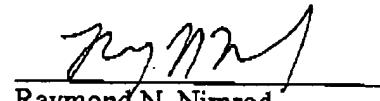


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I hereby certify that this document is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. (571) 273-0571) on May 23, 2005.

Dated: May 23, 2005


Raymond N. Nimrod